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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,475

09/30/2005

Michael George

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EXAMINER

BOESEN, CHRISTIAN C

ART UNIT

PAPER NUMBER

1639

NOTIFICATION DATE

DELIVERY MODE

02/03/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/551,475	<b>Applicant(s)</b> GEORGE ET AL.	
	<b>Examiner</b> CHRISTIAN BOESEN	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-67, 88, 89, 91, 92, 95, 96, 99-104, 107, 109-114, 118, 120, 122, 123 and 125-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/20/2010</u> .                                              | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 47-55,57,59,60,63-67,69-79,83,84,86-89,91-105,107-114,118,120,122,123 and 125-131.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 47-55,57,59,60,63,69-79,83,84,86,87,93,94,97,98,105 and 108.

### **DETAILED ACTION**

This Non-Final Office Action is responsive to the communication received 09/27/2010.

#### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/27/2010 has been entered.

#### **Claim Status**

Claim(s) 1-46, 56, 58, 61-62, 68, 80-82, 85, 90, 106, 115-117, 119, 121 and 124 have been canceled as filed on 09/27/2010.

Claim(s) 101-105, 107-114, 118, 120, 122-123 and 125-131 have been added as filed on 09/27/2010.

Claim(s) 47-48, 51-52, 55, 64, 67-69, 72, 74-75, 83-84, 86-89, 91-93, 95, 99, 107-108, 113, 118 and 120 have been amended as filed on 09/27/2010.

Claim(s) 47-55, 57, 59-60, 63-67, 69-79, 83-84, 86-89, 91-105, 107-114, 118, 120, 122-123, and 125-131 are currently pending.

Claim(s) 47-55, 57, 59-60, 63, 69-79, 83-84, 86-87, 93-94, 97-98, 105 and 108 have been withdrawn.

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Claim(s) 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131 are being examined in this application.

### **Election/Restrictions**

Applicant's election with traverse in the reply filed on 02/20/2009 of group IV, claims 64-67, 70, 88-92, 95-96, 99-105, 107-114, 118, 120, 122-123 and 125-131 is noted.

New/amended claims 64, 67, 88-89, 91-92, 95, 99, 101-105, 107-114, 118, 120, 122-123 and 125-131 are in group IV. Applicant has elected the species of the compound salmeterol BY 630/650 (see claim 92) to prosecute the invention of Group IV.

As per MPEP 803.02, the examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species of compound salmeterol BY 630/650 (see the seventh compound in claim 92) appears allowable. Therefore, according to MPEP 803.02: should the elected species be found allowable, the search of the Markush-type claim will be extended. If the search is extended and a non-elected species found not allowable, the Markush-type claim shall be rejected and claims to the nonelected invention held withdrawn from further consideration. The examination of the Markush-type claims has been extended to include species: XAC - Bodipy 630/650 X (see the first compound in claim 92 and drawing in the rejection below), which is not allowable.

As a non-elected species has been found not allowable, the Markush-type claims have been rejected and claims to the nonelected invention held withdrawn from further consideration.

The elected embodiment, compound salmeterol BY 630/650, meets the limitations of claims 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131. Since

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the nonelected species has been found not allowable, subject matter not embraced by the elected embodiment or the above identified nonelected species is therefore withdrawn from further consideration. The limitations of the elected species in claims 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131 are under examination. It has been determined that the entire scope claimed is not patentable.

This application contains claim(s) 47-55, 57, 59-60, 63, 69-79, 83-84, 86-87, 93-94 drawn to an invention nonelected with traverse in the reply filed on 02/20/2009. A complete reply to the rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### **Priority**

This application for patent is filed under 35 U.S.C 371 of PCT/GB04/01418 (filed on 03/31/2004).

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 04/02/2003. The applicant has filed a certified copy of the 0307559.5 application as required by 35 U.S.C. 119(b).

The priority to a provisional application 60/465,807 filed 04/28/2003 was not entered because the priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the time period is during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. For applications that have entered national stage from an

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international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a prior application, applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) the claim (i.e., the claim required by 35 U.S.C. 119(a)-(d) and (f) and 37 CFR 1.55) for priority to the prior application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

### **Information Disclosure Statement**

The information disclosure statement (IDS) submitted on 09/20/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

### **Previous Rejections and/or Objections**

Any objections and/or rejections raised in the previous Office Action but not reiterated below are considered to have been withdrawn in view of the Applicant's amendments filed on 09/27/2010.

### **Claim Rejections - 35 USC § 103 - New**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Secondary considerations (objective evidence of nonobviousness): a) commercial success; b) long felt need; c) evidence of unexpected results; d) skepticism of experts; and e) copying.

Claims 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131 are obvious over Boring in view of Jacobson 1987 Biochemical Pharmacology, Heefner, Jacobson 1987 FEBS Letters, Jacobson 1988, Sauer, Cherif, Burchard and Buschmann:

**Claims 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boring (1991) Bioconjugate Chemistry volume 2 pages 77 to 88 in view of Jacobson (1987) Biochemical Pharmacology volume 36 pages 1697 to 1707, Heefner (06/24/1999) PCT International Patent Application Publication WO 99/31267 A1, Jacobson (12/1987) FEBS Letters volume 225 pages 97 to 102, Jacobson (1988) Biochemical Pharmacology volume 37 pages 3653 to**

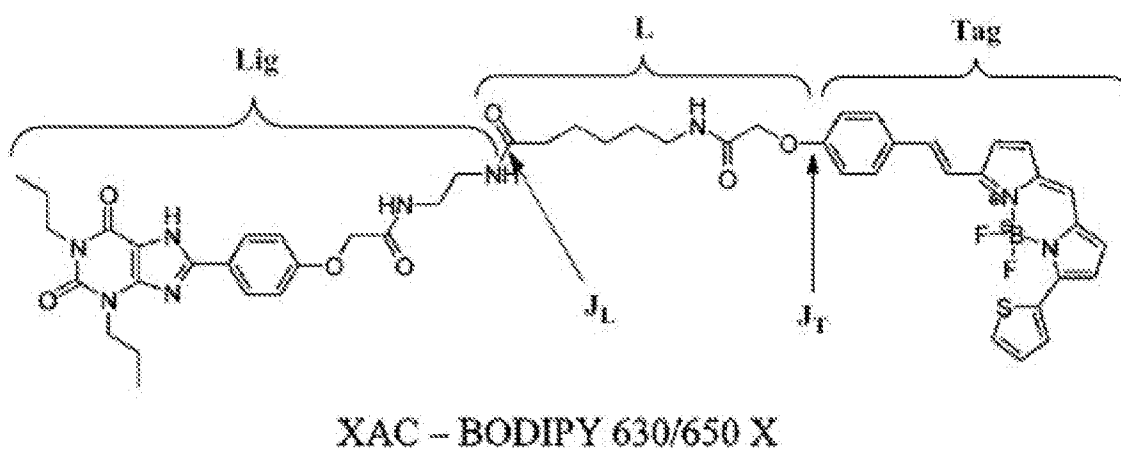


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**3661, Sauer (1998) Bioimaging volume 6 pages 14 to 24, Cherif (04/20/2000) PCT International Patent Application Publication WO 00/22164 A1 which corresponds to English Language US Patent US 6,562,959 B1, Burchard (01/09/2001) US Patent US 6,171,794 B1 and Buschmann (11/27/2002) Bioconjugate Chemistry volume 14 pages 195 to 204.**

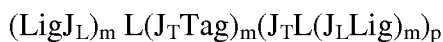
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Applicant's claimed invention is generally directed to fluorescent labeled G protein-coupled receptor (GPCR) binding molecules (for example, a GPCR ligand/fluorescent label compound). The Applicant's invention as set forth in claim 64 encompasses embodiments that are directed towards compounds that are either agonist or antagonist GPCR molecules conjugated to a Bodipy fluorescent dye.



The first compound listed in dependent claim 92 is drawn above and named XAC - Bodipy 630/650 X. This compound meets the claims limitations of independent claim 64 as illustrated above where  $m = 1$  and  $p = 0$  reducing formula I to  $(\text{LigJ}_L)\text{L}(\text{J}_T\text{Tag})$ . Claim 64 recites:

"A compound of formula I



or salts thereof wherein any optically active fluorescent ligand is present as a racemate or as one of its optically active isomers

comprising ligand moiety Lig linked to tag moiety Tag via linker moiety L at linking site or linking functionality  $\text{J}_T$  and  $\text{J}_L$

wherein Lig is selected from a non-peptide a GPCR ligand agonist and a non-peptide GPCR ligand antagonist, wherein the Lig comprises pharmacological

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activity as an agonist or antagonist or GPCR receptor binding and activation or inhibition

L is selected from amine, amide, saturated or unsaturated, substituted or unsubstituted C<sub>1-600</sub> branched or straight chain aliphatic, aromatic, alicyclic and combinations thereof, any of which may comprise one or more heteroatoms selected from N, O, S, P, wherein optional substituents are selected from any C<sub>1-20</sub> aliphatic, aromatic or alicyclic substituents any of which may comprise one or more heteroatoms as hereinbefore defined, hydroxy, thiol, halo, amine, hydrazine, oxo, cyano and carbonyl and combinations thereof, and L is monomeric, oligomeric having oligomeric repeat of 2 to 30 or polymeric having polymeric repeat in excess of 30 up to 300;

m are each independently selected from a whole number integer from 1 to 3;

p is 0 to 3

wherein -Tag is a fluorophore entity -Fl, whereby the compound is of formula I'

$$(\text{LigJ}_L)_m \text{L}(\text{J}_T\text{Fl})_m(\text{J}_T\text{L}(\text{J}_L\text{Lig})_m)_p$$

wherein Fl is selected from 4,4-difluoro-4-bora-3a,4a-diaz-s-indacene dyes and includes a substituent - t- which is a heteroaryl or alkenyl group which performs a fluorescence modifying function which shifts the fluorescence to the red part of the spectrum and raises the absorption max value and

the compound of formula I or I' retains pharmacological activity as a fluorescent GPCR ligand agonist or fluorescent GPCR ligand antagonist for GPCR receptor binding and activation or inhibition."

GPCR binding molecule XAC has been conjugated to multiple different molecules, including fluorescent dyes. Boring teaches XAC conjugated to the fluorescent dye fluorescein or the fluorescent dye NBD (see Abstract, page 86 left top and Table 1 compounds 5p and 5q). Jacobson 1987 Biochemical Pharmacology teaches XAC conjugated to the fluorescent dye fluorescein (see Abstract, page 1706 left bottom and Table 2 compounds 4 and 5). Heefner teaches XAC conjugated to one of three different monochlorofluorescein fluorescent dyes or a sulfofluorescein fluorescent dye (see page 74 line 37, Table 10 Reaction 5, page 81 line 26, page 82 line 22). Jacobson 1987 FEBS Letters teaches XAC conjugated to one of thirteen different

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lipids (see Abstract and Table 1 compounds 16 to 28). Jacobson 1988 teaches XAC conjugated to one of 58 different molecules including peptide, diamino-, thiol-, aldehyde, and halogen substituted derivatives (see Abstract and Table 1 compounds 1 to 58).

Boring, Jacobson 1987 Biochemical Pharmacology, Heefner, Jacobson 1987 FEBS Letters and Jacobson 1988 do not explicitly teach the fluorescent dye is Bodipy 630/650 as in conjugated species XAC - Bodipy 630/650 X (structure drawn in claim 92 and above).

Multiple different biological molecules have been conjugated to the fluorescent dye Bodipy 630/650. Sauer teaches conjugating the nucleotide dUTP with the fluorescent dye Bodipy 630/650 (see Abstract and Figure 1). Cherif teaches conjugating a deoxyribo nucleotide with the fluorescent dye Bodipy 630/650 (see column 5 line 19). Burchard teaches conjugating a deoxyribo nucleotide with the fluorescent dye Bodipy 630/650 (see column 9 line 24). Buschmann teaches conjugating biotin with the fluorescent dye Bodipy 630/650 (see Abstract and Table 2).

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in arriving at the Applicant's invention as claimed with the above cited references before them. The conjugation of XAC to a fluorescent dye to generate a compound used in biological experiments is well known in the art. The conjugation of a biomolecule to the fluorescent dye Bodipy 630/650 to generate a compound used in biological experiments is well known in the art. One of ordinary skill in the art would have recognized the interchangeability of the fluorescent dye fluorescein of Boring for the fluorescent dye Bodipy 630/650 of Sauer, Cherif, Burchard and Buschmann. The conjugated biomolecules (XAC,

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nucleotide dUTP, a deoxyribo nucleotide and biotin) are all small organic molecules of a similar size. The fluorescent dyes (fluorescein, NBD, monochlorofluorescein, sulfofluorescein and Bodipy 630/650)) are all small organic molecules of a similar size. Boring, Jacobson 1987 Biochemical Pharmacology, Heefner, Jacobson 1987 FEBS Letters, Jacobson 1988 teach fluorescent dyes (fluorescein, NBD, sulfofluorescein and there different monochlorofluoresceins) can be conjugated to XAC. Boring, Jacobson 1987 Biochemical Pharmacology, Jacobson 1987 FEBS Letters and Jacobson 1988 teach multiple positions including the C8 position in XAC that tolerate substitutions and retain A<sub>1</sub>-AR binding. Boring, Jacobson 1987 Biochemical Pharmacology, Jacobson 1987 FEBS Letters, Jacobson 1988 teach a linker between XAC and a fluorescent dye wherein XAC that tolerate substitutions and retain A<sub>1</sub>-AR binding. One of ordinary skill in the art would have recognized the interchangeability of the fluorescent dye fluorescein for the fluorescent dye Bodipy 630/650 in conjugating the fluorescent dye to the C8 position in XAC with a known linker. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### **Common Ownership of Claimed Invention Presumed**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### Discussion and Answer to Argument

Applicant is respectfully directed to the above new rejection for an answer to arguments.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 64-67, 88-89, 91-92, 95-96, 99-104, 107, 109-114, 118, 120, 122-123 and 125-131 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application No. 11/576,035.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a fluorescently tagged nucleoside ligand for adenosine A1 and other G protein coupled receptors. The claims of the copending Application 11/576,035 are drawn to an assay using a fluorescently tagged nucleoside ligand for adenosine A1 and other G protein coupled receptors.

Therefore the present claims are obvious in view of the claims of the copending Application 11/576,035.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Discussion and Answer to Argument

Applicants requested the ODP rejection be held in abeyance. Applicants have not provided any specific traversal over the above ODP rejection. Thus, the above rejection is maintained for the reasons of record.

#### **Conclusion**

No claim is allowed.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in *ipsis verbis*, clarification on the record may be helpful). Should

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Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to CHRISTIAN BOESEN whose telephone number is 571-270-1321. The Examiner can normally be reached on Monday-Friday 9:00 AM to 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joanne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian Boesen/  
Examiner, Art Unit 1639

/Jeffrey S. Lundgren/  
Primary Examiner, Art Unit 1639